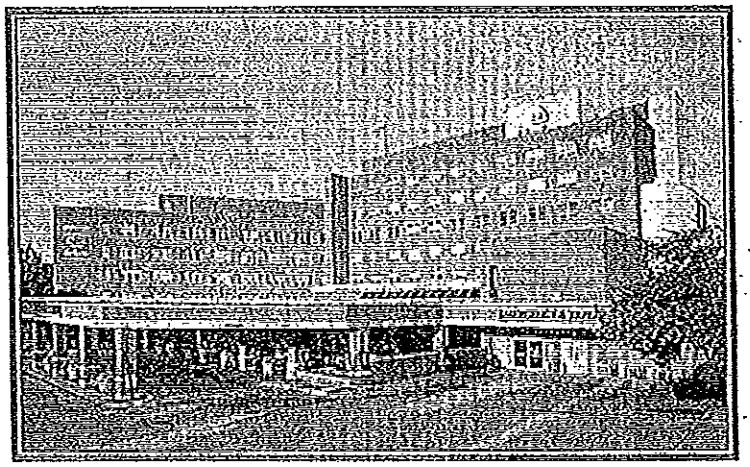
SUBURBAN HOSPITAL

JOHNS HOPKINS MEDICINE



ANNUAL REPORT TO THE MARYLAND HEALTH CARE COMMISSION ON THE COSTS AND BENEFITS OF THE NIH HEART CENTER AT SUBURBAN HOSPITAL

July 1, 2012 through June 30, 2013 / Fiscal Year (FY) 2013

Filed Pursuant to Condition 2 of the Certificate of Need Issued on July 21, 2005

November 25, 2013

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INTRODUCTION

The Certificate of Need authorizing Suburban Hospital ("Suburban") to implement a cardiac surgery, research, and training program directed Suburban to submit a written report each year, providing an "ongoing evaluation of the benefits and costs of the [OHS] program." Annual reports must "be in a format . . . acceptable to the Commission" and are due within 150 days after the end of Suburban's fiscal year.

In response to a Suburban inquiry, Commission staff advised that annual reports should include:

- "a statement of program goals and objectives, including a description of program priorities over the first three years of operation;"
- "definitions of the program benefits and costs to be measured and the specific measurement scale to be applied;"
- "a description of the System which will be employed to acquire the necessary data to measure community benefits and costs of the program;"
- "An analysis of community benefits and costs during the annual reporting period."

Commission staff also advised that annual reports should (1) "focus on community benefits and costs in the Metropolitan Washington regional service area . . . and measure the impact on existing programs in [this] area"; and (2) "provide documentation and specific data to support the analysis of community benefits and costs."[1] (ref: September 22, 2006 letter from Pamela Barclay, Director, Center for Hospital Services, to Andrew L. Solberg.)

This filing is Suburban Hospital's EIGHTH Annual Report.

[1] The Metropolitan Washington Regional Service Area includes Montgomery, Prince George's, Calvert, Charles, and St. Mary's Counties and Washington, D.C.

EXECUTIVE SUMMARY

In Fiscal Year (FY) 2013, the NIH Heart Center at Suburban Hospital continued to provide extraordinary care, besting both National and Maryland quality benchmarks, in some instances by large margins, as demonstrated by information from the Society of Thoracic Surgery (STS) and American College for Cardiology (ACC) databases. During this same twelve month period, the OHS (Open Heart Surgery)/PCI (Percutaneous Coronary Intervention) program at Suburban Hospital saved payers nearly $5.2 million when the cost of care at Suburban Hospital is compared with the costs that would have been incurred had procedures performed at Suburban Hospital been performed elsewhere. In addition, the collaborative research program involving Suburban Hospital and the National Heart, Lung & Blood Institute of the National Institutes of Health ("NHLBI") continues to support relevant and significant translational cardiovascular research. Finally, Suburban Hospital continues to exceed the CON-imposed cardiac surgery volume requirements and exceeds all quality indicators as compared to both the region and nation as determined by performance relative to the benchmarks of the Society of Thoracic Surgery national data base.

Savings and volume indicators are discussed below. Research, the expanded outreach program, and quality of care are addressed in later sections. The financial benefits resulting from the initiation of a cardiac surgery and elective angioplasty program at Suburban are related in Table 1:

Table 1
Financial Benefit in FY'13
Resulting From Initiation of
OHS/Elective PCI at Suburban

Category		Amount
Research*	$	5,000,000
Savings to Payers	$	5,193,328
Uncompensated Care: Charity Care	$	514,369
Uncompensated Care: Bad Debt	$	716,958
Outreach - Incremental*	$	70,000
TOTAL FINANCIAL BENEFIT	**$**	**11,494,655**

*Estimated FY13 Research benefit representing Operating Revenue from cardiac surgery research efforts

PROGRAM DISCUSSION

I. Savings

The case-mix adjusted average charge per case for OHS/PCI care at Suburban Hospital continues to be significantly lower than comparable charges at the four other OHS/elective PCI providers in the metropolitan Washington region (the "Region") where these cases would have been performed if Suburban Hospital did not provide cardiac surgery and elective angioplasty care. As demonstrated in Table 4, for the 12-month period ending June 30, 2013 payers and patients saved nearly **$5.21 million** as a result of the initiation and continuance of cardiac surgery and elective angioplasty services at Suburban Hospital.

To identify savings, Suburban Hospital first used HSCRC data to compare the case-mix adjusted average charge per case for cardiac surgery and angioplasty at Suburban with charges for similar care at Washington Adventist Hospital ("WAH") and Prince George's Hospital Center ("PGHC"), the two Maryland-based OHS/elective PCI providers in the Region. As shown in Table 2, below, Suburban's charges are 13.8% favorable to the charges for OHSI at WAH and even greater, at 29.8% favorable, compared with PGHC. Similarly, Suburban's charges for PCI ("angioplasty") are 29.8% favorable to WAH and 30.4% favorable to PGHC.

Table 2
SH Case mix Adjusted Avg Charge Per Case Compared to Other Maryland OHS Providers

	OHS		PCI	
Maryland Hospital Comparison	Avg Appr Chg Per case	% Difference per case	Avg Appr Chg Per case	% Difference per case
Suburban	$63,117	-	$27,892	-
WAH	$71,813	13.8%	$36,206	29.8%
PGHC	$81,929	29.8%	$36,384	30.4%

As the Commission well knows, comprehensive charge data are not available for Washington, D.C. based OHS providers; however, analysis of Medicare data shows that the average case-mix adjusted Medicare payments for OHS care at Suburban is favorable to Medicare payment for similar care at Washington Hospital Center ("WHC") and George Washington University Hospital ("GWUH"), two D.C. based OHS providers.

As shown in Table 3[2], Suburban's average adjusted reimbursement per Medicare OHS case ($45,926) is 38.0% favorable to Medicare payment to WHC ($63,384) for similar care. The difference between Medicare payments to Suburban and GWUH for similar care is also significant, at 35.2% favorability.

Similar differences exist for angioplasty provided at Suburban when compared to Medicare reimbursement for angioplasty provided at WHC (24.6% favorability) and George Washington (22.0% favorability).

Table 3
SH Average Medicare Payments Per Case Compared to DC Providers

Hospital	OHS		PCI	
	Avg Medicare Pmt Per Case	% Difference per case	Avg Medicare Pmt Per Case	% Difference per case
Suburban	$45,926	-	$21,824	-
WHC	$63,384	38.0%	$27,184	24.6%
GWU	$62,069	35.2%	$26,620	22.0%

[2] Suburban assumed that the difference between Suburban's case mix adjusted Medicare payments and those of the Washington, D.C. providers reflect the difference in payments for all payers.

Savings associated with the differences related above are reflected in Table 4. As noted there, for the twelve month period ending June 30, 2013, patients and payers saved in excess of $3.6 million for OHS cases and greater than $1.5 million in terms of PCI cases as a result of cardiac surgery and angioplasty being available at Suburban Hospital. As expected, the number of cases that would have been performed at the two DC-based providers is greater than the number of cases redirected from the two Maryland providers.

Table 4

Savings to Payers Resulting from OHS and PCI Care Provided at Suburban

	OHS			PCI		
	Savings Per Case	Allocated Cases	Savings	Savings Per Case	Allocated Cases	Savings
Md. Hospitals						
WAH	$8,695	49	$426,077	$8,313	59	$490,475
PG	$18,812	20	$376,233	$8,491	15	$127,368
SUBTOTAL, Savings to Payers, MD hospitals			$802,311			$617,842
DC Hospitals						
WHC	$17,458	154	$2,688,526	$5,360	169	$905,791
GW	$16,143	9	$145,287	$4,796	7	$33,570
SUBTOTAL, Savings to Payers, DC hospitals			$2,833,813			$939,361
TOTAL, MD+DC			$3,636,124			$1,557,204

Total Savings to Payers (OHS + PCI) = $3,636124 + $1,557,204 = $5,193,328

II. Cardiac Surgery Volumes

On August 30, 2006, the Commission issued its Final First-Use Approval for the OHS/PCI program at Suburban. As related in the Commission's Order, this action authorized "full implementation of cardiac surgery [and] percutaneous coronary intervention services." Suburban, accordingly, was required to achieve the minimum volume standards within 24 months of that action, i.e., by August 31, 2008. During the time period September 1, 2006 through August 31, 2007, there were 188 CON defined cardiac surgery cases performed at Suburban. During the time period September 1, 2007 through August 31, 2008, the actual first year "counted" by the MHCC, there were 215 CON-defined cardiac surgery cases performed at Suburban. During the time period September 1, 2008 through August 31, 2009, there were 226 CON defined cardiac surgery cases performed at Suburban Hospital. During the time period September 1, 2009 through August 31, 2010, there were 242 CON defined cardiac surgery cases performed. During the time period September 1, 2010 through August 1, 2011, there were 223 CON defined cardiac surgery cases performed. In Suburban Hospital's 6th annual report filing, it was recommended that volume report time periods be altered to align with the hospital's fiscal year definition (July 1 thru June 30). During the time period July 1, 2010 through June 30, 2011, the CON volume remained constant at 223 cases. In fiscal year 2012 Suburban Hospital's CON defined open heart surgery volume reached 245 cases. And in the most recent fiscal year (FY 2013, representing the time period spanning July 1, 2012 thru June 30, 2013) Suburban hospital performed 228 CON defined cardiac surgery procedures. A FY13 volume graphical depiction is provided in **Appendix C.**

GOALS AND OBJECTIVES

The goals of Suburban's cardiac surgery, elective and emergency angioplasty, research and training program, operated in conjunction with its partners, NHLBI and Johns Hopkins Medicine ("Johns Hopkins") are as related in the Suburban CON application.

> *Following is a summarized report on the status and progress towards each identified goal. Suburban Hospital shall provide to the Commission additional information related to any specific individual goal upon request.*

Goal 1: Provide Excellent Care

The primary goal of the program is to produce clinical outcomes and patient satisfaction equal to those experienced by Johns Hopkins and other high-quality programs as measured by comparative data from the Society of Thoracic Surgeons' National Cardiac Database. Patients undergoing a cardiac surgical procedure at Suburban are enrolled in this database, which includes over 1.3 million patients.

All patients receiving care at Suburban are enrolled in national databases. Cardiology patients studied in the catheterization lab suite are entered into the American College of Cardiology Registry; cardiac surgery patients are enrolled in the Society of Thoracic Surgeons' National Cardiac Database. Suburban's cardiac surgery program received 3 stars for quality from the STS which is the highest score achievable. As related in the following table, from the most recent cumulative data (May 2006 through December 2012) issued by the Society of Thoracic Surgeons, the care provided at Suburban Hospital exceeds all quality indicators when compared to the national and regional benchmarks.

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NIH Heart Center at Suburban Hospital

Quality Indicators from the Society of Thoracic Surgery National Cardiac Database

May 2006 through December 2012 – Cumulative

	National Standard	Suburban Hospital	Regional Group
Risk Adjusted Mortality	2.1	1.6	2.2
Operative Mortality O/E ratio	1.1	0.8	1.2
Re-ops for bleed %	2.4	3.2	2.5
Sternal infection %	0.3	0.0	0.3
Leg infection %	0.4	0.1	0.4
Stroke %	1.4	0.5	1.4
AFib post op %	24.3	11.8	23.3
High risk patients % (Class NYHA IV+CHF)	9.3	12.9	8.6
Urgent CABG %	52.6	63.5	51.0
Pre-op Unstable Angina% (CABG)	30.6	39.4	36.9
Pre-op Arrhythmia % (CABG)	9.4	13.6	9.9
Pre-op Cardiogenic Shock %	1.7	3.1	1.7
Median Post Op LOS:			
CABG	7.0	4.0	7.0
Valve	7.1	4.1	7.2
CABG/Valve	8.4	7.1	7.7
Readmission rate %	10.1	7.1	11.0
* Anti-Lipid @ d/c %	95.1	93.8	94.6
* B Blocker @ d/c %	94.4	94.6	94.0
* ASA @ d/c %	96.5	99.2	96.3
* Cardiac Rehab %	89.1	100	89.1
Mitral valve repairability index		100	
Patient satisfaction		95th percentile	

Information based on Society of Thoracic Surgeons (STS) national Cardiac Database

* Medication at Discharge (D/C) reflects CABG patients

Goal No. 2: Perform Cardiovascular Surgery Research of National Significance

Suburban Hospital's renowned cardiovascular surgeons continue to work closely with the NHLBI to develop and support significant translational research. A list of ongoing and completed research efforts is provided in **Appendix A.**

Among the other significant research performed, Suburban is extremely proud to report that during this fiscal year Dr. Keith Horvath performed the 2nd transmyocardial laser revascularization and stem cell treatment case in the world.

With the Suburban Hospital integration with Johns Hopkins Medicine, Dr. Theodore Abraham continues to serve as Associate Dean for Research in the National Capital Region. Dr. Abraham collaborates with the NHLBI leadership to oversee the research activities of this project in close consultation with the NHLBI scientific director and clinical director. NIH and Suburban Hospital leadership meet on a bi-annual basis and as-needed to discuss progress and growth of research efforts.

Goal No. 3: Offer an Innovative Training Program

Training the next generation of academic cardiac surgeons and cardiologists is another goal and unique feature of the Suburban program. NIH has always captured the imagination of young physician scientists, with an environment including both biomedical scientists and physician mentors. Suburban's program supports collaborative efforts extending to post-doctoral fellows and post-baccalaureate students. Research fellows are also currently at work in Cardiac MRI in a joint program between Suburban and NHLBI that began in 1999. With the advent of the OHS program, the depth and breadth of the clinical experience for these fellows have increased. A similar training program for fellows in a joint Suburban/NIH Stroke program also began in 1999.

Goal No. 4: Continuous Process Improvement

As an integral part of the Suburban Hospital program, continued process improvement requires a careful definition of metrics to assess process and outcome variables, and a forthright sharing of best practices, assessed by repeated site visits by peers. Suburban Hospital participates in nationwide programs aimed at process improvement. In addition, the internal review and oversight processes involving Johns Hopkins, NHLBI and Suburban ensure that continued process improvement will be focused on quality outcomes, patient safety and satisfaction, and process efficiencies.

Goal No. 5: Continue to Address Disparities through Expanded Outreach, Prevention, Detection, and Treatment

Suburban Hospital is extremely proud of our continued efforts to extend community outreach to areas that lay beyond the traditional hospital service area definition. A detailed overview of outreach efforts is provided in **Appendix D.**

Objectives:

- Increase recognition of the NIH Heart Center at Suburban Hospital in Southern Maryland through promotion, publications and education.
- Provide financial support in FY 2014 for home scales to MedStar St. Mary's Hospital's Congestive Heart Failure program.
- Create a competitive scholarship fund initiative to support a cardiovascular or cardiac-related program for the Calvert Memorial Hospital Health Ministry Team Network.
- Enhance collaboration and education with the Prince George's County youth via the Youth Garden program and/or Safe Nights at the Suitland Community Center.
- Identify a second site for expanding the Suitland Dine & Learn program by July 2014.
- 50 percent of Senior Shape Exercise Program participants will improve on at least two (2) of the four (4) fitness assessment areas during FY 2014.
- Conduct at least one (1) Freedom From Smoking Cessation Program in Prince George's County.
- Explore opportunities for partnering with at least one (1) Prince George's County hospital and identify areas where the NIH Heart Center at Suburban Hospital can support their cardiovascular health improvement initiatives.

The NIH Heart Center at Suburban Hospital / Johns Hopkins Medicine has strengthened and maintained an ambitious outreach program to low-income, underserved areas that are racially and ethnically diverse. The primary program outreach areas are in Southern Maryland, including Prince George's, Calvert and St. Mary's Counties. Since the submission of last year's report, Suburban Hospital / Johns Hopkins Medicine's Community Health & Wellness Department dedicated $70,000 towards in-kind and financial support of cardiac outreach programs and services for Southern Maryland residents. With that financial support, Suburban Hospital / Johns Hopkins Medicine has funded senior exercise and fitness programs, cardiac programming and initiatives, heart healthy cooking demonstrations, community health events, cardiovascular health education presentations and health screenings to a total of 12,306 Southern Maryland residents, of which 9,646 were from racially and ethnically diverse populations. A comprehensive discussion of the NIH Heart Center at Suburban Hospital / Johns Hopkins Medicine's expanded Southern Maryland outreach efforts is included as Appendix D.

In fiscal year 2012, Suburban Hospital / Johns Hopkins Medicine dedicated $20.4 million dollars in community benefit contributions to support the needs of the community members residing in Montgomery County and Southern Maryland counties. This year in fiscal year 2013, Suburban Hospital / Johns Hopkins Medicine committed $22.6 million dollars. Suburban Hospital / Johns Hopkins Medicine's Community Health & Wellness Department Outreach Program participated in 2,729 events during FY 2013, reaching a total of 86,606 individuals of which, 24,468 represented racially and ethnically diverse populations.

Part of what makes Suburban Hospital / Johns Hopkins Medicine's Southern Maryland cardiovascular outreach so successful is the partnerships that have been created to achieve a shared goal. Suburban has succeeded in collaborating with nearly sixty hospitals, faith-based organizations, senior and recreation centers, non-profit organizations, academic institutions, government agencies and embassies. Through these partnerships in Southern Maryland, Suburban Hospital provided more than 615 cardiovascular health education services and events in FY 2013.

CONCLUSION

The NIH Heart Center at Suburban Hospital continues to evolve and provide high quality, cost effective, and accessible cardiac surgery and emergent and elective angioplasty care to patients in Maryland and the suburban-Washington D.C. market area. As noted above, continued savings to payers have been substantial, outcomes have been outstanding, and patient satisfaction has been high.

Research efforts are proceeding with laboratory work performed by Dr. Keith Horvath and his NHLBI colleagues in the area of transmyocardial laser revascularization, MRI guided valve replacement and xenotransplantation. Clinical research efforts are focusing on the incidence of stroke after cardiac surgery, myocardial protection during cardiac surgery, and ex-vivo work examining the usefulness of nitrite administration to prevent ischemic injury in atrial tissue harvested at operation. The NIH Heart Center at Suburban Hospital is participating in the Cardiac Thoracic Surgery Network (CTSN). This research consortium is testing various surgical approaches to mitral regurgitation and atrial fibrillation.

Suburban Hospital has focused on access and continues to work with other area hospitals without cardiac surgery/elective PCI to facilitate easy, dependable and rapid transport for patients in need.

The large team of expert caregivers at the NIH Heart Center at Suburban look forward to continuing growth in clinical services, research and training. With the recent integration with John's Hopkins and the ongoing partnership with the NHLBI, both organizations are pleased with the program and continue to be very supportive.

Suburban Hospital continues to expand its vigorous community outreach programs and looks forward to furthering expansion and successful preventive efforts in the future.

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Appendix A: Research Protocol Inventory

(CURRENT CT SURGERY)

NIH	*INDUSTRY*
<u>TRIPS STUDY (Dept. of Transfusion Medicine)</u> <u>A PROSPECTIVE STUDY OF TRANSFUSION-TRANSMITTED INFECTIONS Protocol: 01-CC-0231</u> This study will enroll blood donors and prospectively followed blood recipients in order to: 1) establish ongoing surveillance of the incidence of breakthrough infections from transfusion-transmitted agents for which there are existing donor-screening assays (e.g. HBV, HCV, HIV, human T cell lymphotropic virus [HTLV]); 2) monitor the transfusion risk of established infectious agents that are not routinely screened in blood donors including CMV, EBV, parvovirus B-19, HHV-8 [Kaposi's sarcoma virus], and the recently described SEN and TT viruses (possible hepatitis agents); 3) establish a repository of linked donor and recipient samples so that any newly emerging infectious agent can be rapidly evaluated for its threat to the blood supply. Screening started January 2008. Through October 2013, approximately 1290 subjects have been screened, 194 consented and 106 enrolled at this site. <u>Amendment to Protocol:01-CC-0231</u> DTM wishes to expand enrollment at Suburban Hospital (SH) by enrolling heart surgery patients irrespective of blood group and by adding a non-transfused control population. Hence all patients undergoing heart surgery will be eligible for enrollment if they meet other study criteria. The goal of the study will be to follow all consenting heart surgery patients at Suburban Hospital for six months post-transfusion and to measure molecular and serologic evidence of a recent infection temporally associated with blood transfusion. When donor samples are available, phylogenetic linkage	<u>CSTS: Cardiac Surgery Outcomes: Comparing the Comprehensive Unit-Based Safety Program (CUSP) and Translating Evidence into Practice (TRIP) to Passive Reporting. IRB of Record:Hopkins (NA_00042255)</u> Johns Hopkins is spearheading this patient safety initiative. The overall goal of this program is to substantially reduce the mortality, morbidity, and costs of care in patients having cardiac surgery by implementing an interdisciplinary and multifaceted patient safety program, demonstrated in Comparative Effectiveness Research (CER) to improve patient outcomes in 19 hospitals. Specifically, the purpose is to evaluate the combined impact of a patient safety program in cardiac ORs, ICUs, and surgical floors compared to passive feedback of outcomes on SSI (surgical site infections), CLABSI (Central line associated blood stream infections), and VAP (ventilator- associated pneumonia). A waiver of consent was granted to Hopkins from the JHM IRB and Suburban Hospital was added as a Hopkins site. SHRRC granted permission to include Suburban Hospital as a study site June 2011. Participation continues through October 2013.

analysis will be performed to more specifically implicate transfusion as the cause of the infectious event. Enrollment is anticipated to begin in 4th quarter of 2013.	
Cardiothoracic Surgical Network (CTSN) The goal of the Network is to foster a culture of rigorous scientific comparisons and promote the evaluation of newer surgical techniques, technologies, devices, and innovative pharmaceutical and bioengineered products directed at cardiovascular disease. The network enables research teams led by cardiac surgeons to evaluate newer therapies and techniques as they move from laboratory science to broad clinical use. With support from the National Heart, Lung and Blood Institute at the NIH, CTSN provide the infrastructure to develop, coordinate, and conduct multiple collaborative proof-of-concept clinical studies and interventional protocols to improve cardiovascular disease outcomes. Currently there are four studies that have been submitted to the IRBs. 1. SURGICAL INTERVENTIONS FOR MODERATE ISCHEMIC MITRAL REGURGITATION (NA-00045254 Hopkins) Protocol:09-H-0050 A Randomized multi-center trial to evaluate the safety and efficacy of mitral valve repair for moderate ischemic mitral regurgitation in patients diagnosed with moderate ischemic MR with a clinical indication for CABG. The first network subject was enrolled December 2008. Following IRB approval, screening began in February 2009. The study met its enrollment goal of 300 in April 2013. Four subjects have been enrolled at this site. 2. EVALUATION OF OUTCOMES	Improving Handoffs/Transitions of Care for Cardiac Surgery Patients. IRB of Record:Hopkins (NA_00034813) This is a sub-study of the Cardiovascular Surgical Translational Study (CSTS) collaborative project. The overall objective of the study is to identify the potential risks for post-operative cardiac surgery patients' safety in care transitions, and to develop methods and tools to reduce these risks. The focus will be on cardiac surgery patients because of the complexity and severity of their illnesses and their needs for receiving medical care from various practitioners in multiple settings. This study will involve observations of transitions of care/ hand-off processes (from OR to ICU, ICU/floor-if applicable-, and the discharge planning process such as including discharge rounds, etc.), individual observations of care providers, and interviews with individual care providers, all conducted by the research team. Suburban was added as a Hopkins site through the JHM IRB in January 2012. SHRRC granted permission to include Suburban Hospital as a study site in February 2012. Participation continues through October 2013.

(CURRENT CT SURGERY)

FOLLOWING MITRAL VALVE REPAIR/REPLACEMENT IN SEVERE CHRONIC ISCHEMIC MITRAL REGURGITATION (NA_00045277 Hopkins) Protocol: 09-H-0166 The overall objective of this study is to evaluate the safety and efficacy of mitral valve repair and mitral valve replacement for patients with severe ischemic mitral regurgitation (MR). Specifically, this study compares mitral valve repair with annuloplasty and a subvalvular procedure for severe tethering to mitral valve replacement and complete preservation of the sub-valvular apparatus. ° The primary aim of this trial is to evaluate the impact of these two surgical approaches on left ventricular remodeling. ° Secondary aims of this trial include assessment of the impact of these two surgical interventions on cardiac performance, mortality, adverse events, quality of life, functional status, severity of MR, and health resource use. Following IRB approval, screening began in June 2009. There have been two subjects enrolled and one screen failure at this site as of March 2012. The study reached its goal of 250 randomized patients on February 10, 2012. Patients will continue in follow-up for two years per the protocol's schedule of events.	
3. SURGICAL ABLATION VERSUS NO SURGICAL ABLATION FOR PATIENTS WITH PERSISTENT OR LONGSTANDING PERSISTENT ATRIAL FIBRILLATION UNDERGOING MITRAL VALVE SURGERY (NA_00045294 Hopkins) The primary aim of the study is to	A Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Trial of Multiple Dosing Regimens of ABT-719 for the Prevention of Acute Kidney Injury in Subjects Undergoing High Risk Cardiac Surgery (NA_00079223 Hopkins) The study objective is to compare the safety and efficacy of doses of 800 mcg/kg, 1600 mcg/kg and 2100 mcg/kg intravenous

determine if surgical ablation of non-paroxysmal AF is more effective than mitral valve surgery (MVS) alone in reducing incidence of post-MVS AF at 1 year. Inclusion of two different lesion sets in the ablation group (pulmonary vein isolation only [PVI] and a biatrial Maze lesion set) will provide preliminary data to guide development of a follow-up study comparing effectiveness of these 2 lesion sets. In addition to 72-hour continuous rhythm assessment at 1 year (Holter), we will employ weekly transtelephonic monitoring to inform follow-up strategies for future trials of rhythm control in AF. 260 subjects will be enrolled and 255 subjects have been enrolled to date. IRB approval of protocol revisions was granted in June 2009 and CMS approval has been obtained. IRB approval was granted for version 3.2 of the protocol. Enrollment began in February 2010. The study reached its goal of 260 randomized subjects in September 2013. Six subjects were enrolled at our site. Follow up continues as of October 2013 4. <u>MANAGEMENT PRACTICES AND THE RISK OF INFECTIONS FOLLOWING CARDIAC SURGERY (NA_00045301 Hopkins)</u> The overall objective of this observational study is to identify management practices that put patients at risk for infections following cardiac surgery.*The specific aims of this observational study are: a. To identify modifiable management practices (e.g. surgical site preparation, central line management) and patient characteristics (e.g., diabetes) that are predictive of postoperative infections b. To delineate management practice variations that may be associated with higher infection rates among	(IV) infusions of ABT-719 to placebo in subjects who are at risk of Acute Kidney Injury (AKI) and undergoing pre-defined on-pump cardiac surgery. The protocol was reviewed at the SHRRC on December 11, 2012 and has received approval from the Hopkins eIRB. An amendment to the protocol was approved by the eIRB at Hopkins. Screening began in June 2013. Three participants have been randomized and two have screen failed as of October 2013.

participating clinical centers c. To assess how major infections, and the management practices associated with their occurrence, affect hospital resource use and inpatient costs. IRB approval has been granted for the protocol. Enrollment began in Feb 2010 and ended Sep 2010. 149 subjects were enrolled with three screen failures at this site. Over 5100 subjects were enrolled in the observational study. It is anticipated that multiple significant publications will emerge.	
<u>Preliminary Assessment of Direct Intra-myocardial Injection of Autologous Bone Marrow-derived Stromal Cells on Patients Undergoing Revascularization for CAD with Depressed Left Ventricular Function Protocol: 12-H-0078</u> The primary objective is to evaluate the safety and feasibility of direct intra-myocardial injection of autologous bone marrow stromal cells (BMSCs) in adult subjects undergoing cardiac artery bypass graft (CABG) or transmyocardial revascularization (TMR). The protocol has received IRB approval with NHLBI IRB and has received an IND with the FDA. A Site Initiation Visit was conducted on March 19, 2012 and CMRP/CTM has confirmed that all regulatory documents have been received. Screening began and four subjects have been enrolled and five have screen failed as of October 2013.	<u>A Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Trial of Multiple Dosing Regimens of ABT-719 for the Prevention of Acute Kidney Injury in Subjects Undergoing High Risk Major Surgery (NA_00085181 Hopkins)</u> The objectives of this study are as follows: Part 1: To determine the safety and pharmacokinetics of 800 mcg/kg intravenous (IV) infusions of ABT-719 in the first 6 subjects enrolled who are at risk of acute kidney injury (AKI) and undergoing high risk major surgery. Part 2: To compare the safety and efficacy of doses of 800 mcg/kg, 1600 mcg/kg and 2100 mcg/kg IV infusions of ABT-719 to placebo in subjects who are at risk of AKI and undergoing high risk major surgery. Suburban will be participating in Part 2 of the study where up to 340 subjects will be randomized in this multicenter double-blind portion of the study. The protocol has been approved by the SHRRC and the JHM eIRB on July 22, 2013. Enrollment will begin once Part 1 has been completed and the data analyzed.
<u>Cardiovascular Disease Discovery Protocol: 10-H-0126</u> Patients who enter the protocol may require medically indicated cardiothoracic or vascular surgery where diseased or redundant tissue at the surgical site would be extracted. Portions of the tissue/s may be submitted to	

the pathology laboratory at the request of the surgeon. If residual tissue is available that would otherwise be discarded as 'surgical-waste', the investigator with fully informed consent from the patient, may request the tissue/s to study to aid the diagnosis or to enhance the understanding of the disease pathophysiology. It is anticipated that this part of the study will begin in the fourth quarter of 2013.	

CURRENT CARDIOLOGY AND OTHER NIH STUDIES (ACTIVELY ENROLLING AND/OR IN FOLLOWUP)

NIH	*INDUSTRY*
ASTHMA (NHLBI): Role of Genetic Factors in the Pathogenesis of Lung Disease. Protocol: 96-H-0100 This study is designed to evaluate genetic mechanisms of lung disease by surveying polymorphic genes involved in respiratory function and examining gene expression in the lung cells of individuals with pulmonary disease (e.g., alpha 1-antitrypsin deficiency, chronicobstructive pulmonary disease, cystic fibrosis, sarcoidosis). Emphasis will be on defining the distribution of allelic variants of nitric oxide synthase, alpha 1-antitrypsin, and the cystic fibrosis transmembrane conductance regulator genes in patients and in age- and sex-matched healthy individuals in a control population. Screening started January 2006. 73 subjects have enrolled and there have been 12 screen failures through October 2013.	IMPROVE IT: Improved Reduction of Outcomes: Vytorin Efficacy International Trial A Multicenter, Double-Blind, Randomized Study to Establish the Clinical Benefit and Safety of Vytorin (ezetimibe/simvastatin vs. Simvastatin Monotherapy) in High-Risk Patients Presenting with Acute Coronary Syndrome. Protocol: P01403 IRB of Record: WIRB Major objective is to evaluate the benefit of combination eztimibie/simvastatin vs. simvastatin alone in subjects post ACS to decrease Major CV events including: CV death, MI, UA, Revasc (>30 days) or stroke. Screening started April 2006. 14 subjects have enrolled and 1 subject transferred to this site through September 2010. One subject transferred to another site in June 2011. The enrollment phase was completed July 2010 with a final enrollment of 18,141 patients. Follow up continues through October 2013.
CLINSEQ (NHGRI) A Large-Scale Medical Sequencing Clinical Research Pilot Study. Protocol: 07-HG-0002 The main goal of *ClinSeq* is to learn how to do *genome sequencing* in a clinical research setting. Screening started January 2007. There are currently over 1,050 participants enrolled in the ClinSeq study through October 2013. Over 210 of Suburban's referrals have been enrolled in the study.	ALERTS: (AngeLmed for Early Recognition and Recognition of STEMI) Study. IRB of Record: Hopkins (NA_00072878) This is a randomized, prospective clinical investigation with blinded CORE laboratories, and an independent clinical events adjudication committee that will evaluate the effectiveness of the AngelMed Guardian System as compared with the standard of care in reducing the incidence of the composite of death, new Q-wave MI and presentation > 2 hours for thrombotic coronary occlusion events among subjects at a high-risk of recurrent myocardial infarction. The ALERTS Study will enroll up to 3000 consecutive subjects who have been identified as having a high risk of a

CURRENT CARDIOLOGY AND OTHER NIH STUDIES (ACTIVELY ENROLLING AND/OR IN FOLLOWUP)

	MI due to ACS or bypass surgery. The subjects will be implanted with the Guardian System and will be randomized 1:1 to alerting and no alerting after implantation. Half of the subjects will be randomly assigned to the treatment group using the Guardian System with an EXD and alerting turned on and the other half assigned to the control group with the Guardian System alerting turned off, no EXD provided. Patients will know if their devices have alerting enabled. The protocol has been approved by the Suburban Hospital Research Review Committee (SHRRC) and the JHM eIRB. Screening began after site activation in November 2012. One subject has been randomized as of July 2013. There are now 1020 patients enrolled in ALERTS, and 900 patients implanted. Enrollment has been temporarily paused by the sponsor so that the enrollment limit of 1020 is not exceeded. At this milestone, the protocol mandates a sample size look analysis, as well as a potential Early Win analysis.
<u>New Techniques to Evaluate Mitral Regurgitation (NHLBI) Protocol: 10-H-0039</u> The objective of the current pilot study is to explore new 3-dimensional methods of measuring mitral regurgitation severity and compare them with the standard 2D methods. Most prior studies have used the 2D quantitative Doppler method as the current standard for measurement of mitral regurgitant volume. Over the last 5-10 years, the PISA method has become accepted in clinical practice, however, recent 3D studies (looking directly at the PISA hemisphere) have shown that the assumptions involved in these calculations significantly underestimate regurgitant	<u>International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) IRB of Record: Hopkins (NA_00076707)</u> The purpose of the ISCHEMIA trial is to determine the best management strategy for higher-risk patients with stable ischemic heart disease. This is a multicenter randomized controlled trial with a target enrollment of ~8000 patients with at least moderate ischemia on stress imaging. Patients will be assigned at random to a routine invasive strategy (INV) with cardiac catheterization (cath) followed by revascularization plus optimal medical therapy (OMT) or to a conservative strategy (CON) of OMT, with cath and

CURRENT CARDIOLOGY AND OTHER NIH STUDIES (ACTIVELY ENROLLING AND/OR IN FOLLOWUP)

volumes particularly in patients with functional MR. Since real-time 3D echocardiography has been shown to provide accurate results for left ventricular volumes compared with CMR, we propose to use this volumetric method to calculate regurgitant volumes in patients with mitral regurgitation. Specific objectives are: 1) To compare a volumetric 3D echo-derived regurgitant volume with 2D quantitative Doppler-derived regurgitant volume. 2) To compare a volumetric 3D echo-derived regurgitant volume with PISA-derived regurgitant volume. 3) To compare a volumetric 3D echo-derived regurgitant volume with CMR determination of mitral regurgitant volume. Secondary objectives are to assess time of acquisition and analysis for the 3D echo images and to obtain inter- and intra-observer reproducibility for the measurement of 3D regurgitant volumes. Screening started in October 2010 and 11 subjects have been enrolled through October 2013.	revascularization reserved for those with an acute coronary syndrome, ischemic heart failure, resuscitated cardiac arrest or refractory symptoms. The protocol has been approved by the Suburban Hospital Research Review Committee (SHRRC) and the JHM eIRB. Site initiation occurred on 1/14/2013 and screening is ongoing as of October 2013. Two subjects have been enrolled at our site but one subsequently screen failed.
	<u>A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of SAR236553/REGN727 on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome (NA_00079388 Hopkins)</u> The primary objective of this study is to compare the effect of SAR236553 with placebo on the occurrence of cardiovascular events (composite endpoint of coronary heart disease (CHD) death, non-fatal myocardial infarction (MI), fatal and non-fatal ischemic stroke, unstable

CURRENT CARDIOLOGY AND OTHER NIH STUDIES (ACTIVELY ENROLLING AND/OR IN FOLLOWUP)

	angina requiring hospitalization) in patients who have experienced an acute coronary syndrome (ACS) event 4 to 16 weeks prior to randomization and are treated with intensive statin therapy (defined as atorvastatin 40 or 80 mg, or rosuvastatin 20 or 40 mg) or at maximally tolerated dose of these given statins, or other non statin LMT(s). The protocol has been approved by the Suburban Hospital Research Review Committee (SHRRC) and was approved with administrative changes by the JHM eIRB on June 10, 2013. Four subjects have enrolled, two of which screen failed. Screening is ongoing as October 2013.
<u>Contrast-Enhanced Ultrasound Imaging of Carotid Plaque Neovascularization Amendment to (NHLBI) Protocol #11-H-0224</u> The purpose of this study is to evaluate characteristics of carotid plaques using contrast-enhanced ultrasound and MRI in order to identify associations between plaque neovascularization and intraplaque hemorrhage. Subjects with moderate and severe carotid disease will be enrolled. In those subjects scheduled for CEA, imaging findings will be compared with histopathology of the excised plaque. Subjects will be followed for 3 years from the time of their imaging studies to determine which imaging features predict increased risk for any type of cardiovascular event. The unique features of this study are: (1) Multimodality characterization of plaque morphology. Plaque vascularity will be assessed by contrast-enhanced ultrasound and intraplaque hemorrhage and lipid core will be assessed by MRI. (2) Imaging findings will be validated	<u>A Randomized, Multi-center, Placebo-controlled, Parallel-group Study to Determine the Effects of AMG 145 Treatment on Atherosclerotic Disease Burden as Measured by Intravascular Ultrasound in Subjects Undergoing Coronary Catheterization: GLAGOV (NA_00081856 Hopkins)</u> This is a Phase III, multi-center, double-blind, randomized, placebo-controlled study evaluating the effect of AMG 145 on coronary atherosclerotic disease burden as assessed by intravascular ultrasound (IVUS) at baseline and following 78 weeks of treatment in subjects with coronary artery disease. Subjects will be randomized 1:1 into 2 treatment groups: AMG 145 420 mg Q4W SC or placebo Q4W SC. Randomization will be stratified for balance by geographic region. Approximately 950 subjects (475 AMG 145 and 475 placebo) will be randomized. The protocol has been approved by the Suburban Hospital Research Review Committee (SHRRC) and was approved with administrative changes by the JHM eIRB on July 15, 2013. Site initiation occurred on 10/31/2013.

CURRENT CARDIOLOGY AND OTHER NIH STUDIES (ACTIVELY ENROLLING AND/OR IN FOLLOWUP)

by histopathology in subjects undergoing CEA (3) Since previous studies of imaging morphology of plaques have little or no information on lipid levels and effectiveness of statin therapy, we will correlate plaque morphology with lipid profiles and serum biomarkers on current medical therapy. (4) Subjects will be followed prospectively to determine features of a local carotid lesion that may predict cardiovascular events in other territories The study has been approved at NIH and the Suburban Hospital Research Review Committee (SHRRC). Collaboration is being done with Suburban Hospital to identify potential participants via clinically indicated ultrasound exams. Participants will be enrolled at the NIH Clinical Center. Screening started June 2012. One subject screen failed as of October 2013.	
	<u>ImageReady™ MR Conditional Pacing System SAMURAI Study (NA_000 Hopkins)</u> The objective of this study is to collect data to confirm the safety and effectiveness of the ImageReady™ MR Conditional Pacing System when used in the MRI environment under the labeled Conditions of Use. The SAMURAI Study is a prospective, open-label, two-group randomized clinical study with parallel groups to be conducted at multiple centers globally. A 2:1 (MRI:Control) randomization will be used in the SAMURAI Study; the overall study sample size is 363 subjects (242 MRI, 121 Control). The protocol was presented to the Suburban Hospital Research Review Committee (SHRRC) in May 2013 and was approved by the JHM eIRB on July 1,

CURRENT CARDIOLOGY AND OTHER NIH STUDIES (ACTIVELY ENROLLING AND/OR IN FOLLOWUP)

	2013. Enrollment has not started.

COMPLETED CT SURGERY RESEARCH

NIH	*INDUSTRY*
<u>Cardiac Ischemia Study (Atrial appendage) (NHLBI):</u> We hypothesize that nitrite administration to atrial tissue in an ex-vivo study will demonstrate increased tolerance to ischemic stress compared to atrial tissue not exposed to nitrite. Furthermore, we propose that this cytoprotective effect of nitrite administration will demonstrate equivalency to cytoprotection in response to ischemic preconditioning. Finally, we would employ this tissue to identify nitrite mediated genomic, proteomic and metabolomic modifications in human myocardium, thereby identifying the biological programs orchestrating the cytoprotective properties of nitrite in the human heart. 79 subjects were screened from Apr 2007 to Oct 2007. 38 subjects were consented and tissue was obtained in 25 subjects.	*MEND CABG II:* A Randomized, Double-Blind, Placebo-controlled, Multi-center Study to Evaluate the Cardioprotective Effects of MC-1 in Patients Undergoing High-Risk Coronary Artery Bypass Graft (CABG) Surgery (follow-up only). The principal goal of this study is to determine the effect of MC-1 on the combined incidence of cardiovascular death and nonfatal myocardial infarction (MI) up to and including 30 days following CABG surgery compared with placebo. 3023 subjects were randomized at 130 sites in USA, Germany, and Canada from Oct 2006 to Sep 2007. Conclusions: Among intermediate to high-risk patients undergoing CABG surgery, MC-1 (250 mg/day) given immediately before and for 30-days following surgery does not reduce CV death or non-fatal MI. 21 subjects were enrolled at this site from Nov 2006 to Sep 2007.
<u>Cerebral lesions and outcomes after cardiac surgery</u> CLOCS and CLOCS LITE (NINDS): An observational study analyzing cerebral lesions using MRI pre & post cardiovascular surgery. This study was conducted in collaboration with NINDS. From Oct 2006 to Jan 2007, 54 subjects were screened, 23 consented, and 9 subjects enrolled. In Jan 2007, the protocol was revised (CLOCS LITE) to only include MRI post surgery. 8 subjects were enrolled.	<u>The Effect Of Acadesine On Clinically Significant Adverse Cardiovascular and Cerebrovascular Events In High-Risk Subjects Undergoing Coronary Artery Bypass Graft (CABG) Surgery Using Cardiopulmonary Bypass (Protocol No. P05633): RED-CABG Trial (Reduction in Cardiovascular Events by AcaDesine in Subjects Undergoing CABG)</u> The principal goal of the study is to evaluate the clinical benefit of acadesine in reducing the incidence of ischemia-reperfusion injury resulting from coronary artery bypass graft (CABG) surgery, as measured by the first occurrence of any component of the composite primary endpoint of all-cause death, severe left ventricular dysfunction (SLVD), or non-fatal stroke occurring during or following

COMPLETED CT SURGERY RESEARCH

	CABG surgery through postoperative day (POD) 28. The key secondary objective is to evaluate the clinical benefit of acadesine with respect to incidence of the first occurrence of any component of the composite of cardiovascular death, SLVD, or non-fatal stroke occurring during or following CABG surgery through POD 28. Approximately 7,500 subjects will be enrolled at approximately 300 sites. The study was approved at the Suburban IRB April 2009 meeting. Through July 2010, 89 subjects have been screened and 18 subjects have been enrolled at this site. On July 29, 2010, the DSMB met for the second planned interim and safety analysis (30% or 2,250 subjects with complete POD28 visit data) to review the adjudicated events and assess futility. During this meeting, the DSMB reviewed available data on 2,864 subjects enrolled in the RED-CABG study. The analysis led the DSMB to recommend that enrollment be stopped. This recommendation from the analysis was exclusively based on futility to achieve the targeted efficacy goals per the protocol. It was not determined by any potential safety issues in the review by the DSMB. Enrollment closed in July 2010. This site's close-out visit was done November 30, 2010 at which time the IRB was notified.
<u>Cardiac Ischemia Study (NHLBI) Pilot study to assess the proteome in human atrial tissue (Atrial appendage – part 2) Protocol:08-H-N037</u> The objective of this study is to establish whether the right atrial proteome shows distinct differences between diabetic and non-diabetic subjects and to evaluate whether the different classes of anti-diabetic therapies modulate this proteomic signature. Screening started May 2008. Through September 2011, 209 subjects have been screened & 78 subjects have been enrolled. The study was closed September 2011 and the IRB notified.	<u>A Randomized, Multicenter, Double-Blind, Group-Sequential Study to Evaluate the Efficacy, Immunogenicity, and Safety of a Single Dose of Merck 0657nI Staphylococcus aureus Vaccine (V710) in Adult Patients Scheduled for Cardiothoracic Surgery</u> This study will evaluate the ability of the Merck 0657nI *Staphylococcus aureus* vaccine (hereafter referred to as V710) to prevent serious *S. aureus* infections (i.e., bacteremia and/or deep sternal wound infections, including mediastinitis) for a defined period of time following cardiothoracic surgery. The protocol has

COMPLETED CT SURGERY RESEARCH

	been submitted to the Suburban Hospital Research Review Committee and the JHM eIRB. The sponsor terminated the study prior to our site receiving approval. The study was withdrawn from the IRB in June 2011.

COMPLETED CARDIOLOGY STUDIES

NIH	*INDUSTRY*
<u>Endothelial Progenitor Cell Mobilization and Endothelial Function in Patients with Coronary Artery Disease Undergoing Cardiac Rehabilitation</u> Patients with CAD have reduced circulating endothelial progenitor cells (EPCs), which may contribute to endothelial dysfunction and cardiovascular risk. We hypothesized that cardiac rehabilitation might increase EPCs, with improvement in endothelial function. 50 subjects enrolled.	<u>Targegen (TG001-03):</u> A Phase 1-2, Multicenter, Randomized, Double-Blind, Placebo Controlled, Prospective Study to Evaluate the Safety and Potential Efficacy of Single, Increasing Doses of TG100-115, a Phosphatidylinositol-3 Kinase Inhibitor, in Subjects Undergoing Percutaneous Coronary Intervention for Acute ST Elevation Myocardial Infarction. (NIH collaborated with followup procedure) (completed 11/07) 6 subjects enrolled
<u>Mechanism and Vascular Effects of Endothelial Progenitor Cell Mobilization in Patients with Coronary Artery Disease undergoing Cardiac Rehabilitation</u>: (Study # 06-H-0122) A Prospective NHLBI study to demonstrate a relationship between EPC mobilization and increased whole blood nitrite as a marker of improved vascular NO bioactivity due to EPC mobilization, and 2) Determine EPC gene expression profiles, with a focus on activation or suppression of genes whose products regulate intravascular redox potential, apoptosis and growth factor and cytokine secretion in subjects with CAD undergoing Cardiac Rehabilitation. It is hypothesized that activation or suppression of critical genes in EPCs at baseline or during exercise may determine EPC mobilization, endothelial differentiation and vascular repair potential as evidenced by increased intravascular NO.	<u>Triton TIMI-38:</u> A Phase 3, multicenter, randomized, parallel-group, double-blind, double dummy, active-controlled study to test the hypothesis that CS-747 plus aspirin is superior to clopidogrel plus aspirin in the treatment of subjects with acute coronary syndrome (ACS) who are to undergo percutaneous coronary intervention (PCI), as measured by a reduction in the composite endpoint of cardiovascular (CV) death, nonfatal myocardial infarction (MI), or nonfatal stroke at a median follow-up of at least 12 months. (completed 11/07) 13 subjects enrolled
<u>IL-1 Trap (NHLBI):</u> <u>Effects of Interleukin-1 Inhibition on C-</u>	<u>ZEUS: Open-Label, Phase 2 Study of the Safety and Efficacy of ß-Methyl-*p*-[^{123}I]-Iodophenyl-Pentadecanoic Acid</u>

COMPLETED CARDIOLOGY STUDIES

<u>Reactive Protein Levels, Endothelial Progenitor Cell Mobilization and Endothelial Function in Patients with Coronary Artery Disease :</u> The objective of the present study is to demonstrate the potential of an investigational biological agent-- rilonacept --as adjunctive treatment for CAD, by examining effects of this agent on CRP levels, endothelial progenitor cell mobilization and endothelial function in a randomized, double-blind, placebo-controlled phase II clinical trial. Screening started April 2007. 2 subjects have enrolled and there have been 8 screen failures through April 2008. Recruitment at this site stopped April 2008.	<u>(Iodofiltic Acid I 123) for Identification of Ischemic Myocardium Using Single Photon Emission Computed Tomography (SPECT) in Adults with Symptoms Consistent with Acute Coronary Syndrome (ACS).</u> The principal goal is to evaluate the performance characteristics (sensitivity & specificity) of iodofiltic acid I 123 imaging for detection of myocardial ischemia in patients that present in the Emergency Department with suspected ACS. To evaluate the safety of a single injection of iodofiltic acid I 123 in patients suspected of myocardial ischemia related to ACS. Screening started September 2007. 2 subjects have enrolled through December 2008. Recruitment stopped in May 2008. The IRB noted the study termination at this site January 2009.
<u>An Intravenous, Open-Label, Single-Dose Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of rhLCAT in Patients with Stable Coronary Artery Disease (NHLBI) Protocol: 12-H-0092</u> Subjects with coronary artery disease will receive a single dose of rhLCAT and be followed for 28 days. Three cohorts consisting of 4 subjects will receive one of three doses of rhLCAT. All subjects at the lower dose will complete dosing prior to subjects at the next higher dose receiving study infusions. The goal is to obtain information on the pharmacokinetics and pharmacodynamics of rhLCAT in subjects with coronary artery disease and assess safety and tolerability. The study was approved at NIH and the Suburban Hospital Research Review Committee (SHRRC). Subjects #10, 11, and 12 being treated the last week of June 2012 at NIH. Four subjects were screened at Suburban	<u>PLATO: A Randomized, Double-Blind, Parallel Group, Phase 3, Efficacy and Safety Study of AZD6140 Compared with Clopidogrel for Prevention of Vascular Events in Patients with Non-ST or ST elevation Acute Coronary Syndromes (ACS).</u> The principal objective of this study is to test the hypothesis that AZD6140 is superior to clopidogrel for the prevention of vascular events in patients with non-ST or ST elevation acute coronary syndromes (ACS). It is designed to test the hypothesis that the greater and more consistent levels of ADP receptor inhibition shown with AZD6140 compared with clopidogrel will lead to fewer recurrent thrombotic events. Screening started December 2006. 22 subjects have been consented, 17 subjects have been randomized and there have been 5 screen failures through March 2009 at this site. The study database lock was March 2009. The Suburban Hospital site

COMPLETED CARDIOLOGY STUDIES

and one screen failed.	Close-Out visit was conducted June 2, 2009 and the Suburban IRB was notified on this date.
	<u>CHAMPION PCI: A clinical trial comparing treatment with cangrelor to clopidogrel in subjects who require percutaneous coronary intervention:</u> The primary objective of this study is to demonstrate that the efficacy of cangrelor (combined with usual care) is superior to that of clopidogrel, in subjects requiring percutaneous coronary intervention (PCI) as measured by a composite of all-cause mortality, myocardial infarction (MI), and ischemia-driven revascularization (IDR) at 48 hours and 30 days. Screening started May 2008. 1 subject was enrolled and there were 2 screen failures through May 2009. Enrollment stopped May 2009 when interim analyses indicated the CHAMPION program would not meet efficacy endpoints. The Suburban Hospital site Close-Out visit was conducted August 6, 2009 and the Suburban IRB was notified on this date.
	<u>CHAMPION PLATFORM: A clinical trial comparing treatment with cangrelor (in combination with usual care) to usual care, in subjects who require percutaneous coronary intervention :</u> The primary objective of this study is to demonstrate that the efficacy of cangrelor (combined with usual care) is superior to that of usual care, in subjects requiring percutaneous coronary intervention (PCI) as measured by a composite of all-cause mortality, myocardial infarction (MI), and ischemia-driven revascularization (IDR) at 48 hours and 30 days. Screening started April 2007. 16 subjects have enrolled and there have been 17 screen failures through June 2009. Enrollment stopped May 2009 and follow-up was completed March 2010. The Suburban Hospital site Close-Out visit

COMPLETED CARDIOLOGY STUDIES

	was conducted April 23, 2010 and the Suburban IRB was notified on this date.
	<u>DEfibrillators To REduce Risk by MagnetIc ResoNance Imaging Evaluation (DETERMINE)</u> The DETERMINE trial is a multi-center, randomized study of patients with coronary artery disease (CAD) and mild to moderate left ventricular (LV) dysfunction. The primary objective of this study is to test the hypothesis that Implantable Cardioverter Defibrillator (ICD) therapy in combination with medical therapy in patients with an infarct size ≥ 10% of the left ventricular mass improves long term survival compared to medical therapy alone. 3 subjects have been enrolled in the registry as of July 2009. Recruitment was suspended in July 2009 by the IRB pending the identification of a new Principal Investigator. On April 12, 2010 the protocol was terminated at Suburban Hospital.
	<u>TIMI 38 CSR: The TIMI 38 Coronary Stent Registry(CSR): Long-Term Follow Up of Subjects with PCI and Stenting for ACS.</u> Major objective is to collect long term followup in relation to stenting and thienopyridine administration. Screening started May 2007. Enrollment and follow up have ended. Ten subjects were consented at this site. The database was locked in September 2010. The IRB was notified October 2010 that the registry was closed at this site.
	<u>Secondary Prevention of Small Subcortical Strokes (SPS3) (NINDS)</u> (Extramural study) The primary aim of the study is to define efficacious therapies for prevention of stroke recurrence and cognitive decline in patients with symptomatic small subcortical stroke/subcortical TIA. The specific hypotheses to be tested are 1.) Combined antiplatelet therapy will reduce recurrent stroke by 25% relative to aspirin therapy alone and 2.) Aggressive blood

COMPLETED CARDIOLOGY STUDIES

	pressure lowering will reduce recurrent stroke by 25% relative to usual management. This is a multicenter phase III randomized 2X2 controlled trial which will randomize 3000 subjects who have had MRI documented symptomatic small subcortical strokes (S3)/subcortical TIA within prior 6 months into four equal cells. The interventions will be 1.) Antiplatelet therapy: aspirin (325 mg/d, enteric coated) vs. aspirin + clopidogrel (75 mg/d) (double-blinded) and 2.) Targeted blood pressure control: usual (systolic 130-149) vs. aggressive (systolic < 130 mmHg) (blinded event adjudication). The Suburban IRB approved the study in August 2009. Screening began in the first quarter of 2010. Of the 18 subjects with small vessel disease, there were no suitable subjects who met the inclusion and did not have any of the exclusion criteria. The study closed at Suburban Hospital October 2010. Enrollment has been challenging as there were no suitable patients who met inclusion criteria.
	<u>SATURN : Study of Coronary Atheroma by InTravascular Ultrassound: Effect of Rosuvastatin Versus Atorvastatin Protocol: D356IC0001 IRB of Record: WIRB</u> The primary objective of this study is to compare the effects of Rosuvastatin 40 mg with Atorvastatin 80 mg on atheroschlerotic disease burden as measured by intravascular ultrasound in patients with coronary artery disease CAD. The last subject was randomized in May 2009. Screening began at this site February 2009 and 1 subject has been randomized and 8 subjects have screened failed as of September 2010. Enrollment has been completed as of May 2009 and follow-up has been completed. Close-out visit was conducted on September 15, 2011 and an

COMPLETED CARDIOLOGY STUDIES

	IRB closure letter was sent on the same date. WIRB acknowledged receipt of study closure notification and closed the study effective 9/19/11.
	<u>A Multi-center, Randomized, Double-Blind, Placebo- Controlled Study to Evaluate the Safety and Efficacy of SCH 530348 in Addition to Standard of Care in Subjects With Acute Coronary Syndrome: Thrombin Receptor Antagonist for Clinical Event Reduction in Acute Coronary Syndrome (TRA·CER) PROTOCOL NUMBER: P04736 IRB of Record: WIRB</u> The primary objective is to evaluate the hypothesis that SCH 530348 added to standard of care will reduce the incidence of atherothrombotic ischemic events relative to standard of care alone, as measured by the composite of cardiovascular death, myocardial infarction (MI), stroke, recurrent ischemia with rehospitalization, and urgent coronary revascularization. The patient population includes subjects with Acute Coronary Syndrome (ACS). IRB approval was granted on 7/31/09 with subsequent activation to screen/enroll at the end of September, 2009. 4 subjects have been enrolled through June 2010. Tracer met its enrollment goal of 12,500 at the beginning of June and enrollment was completed June 4, 2010. Close-out visit was conducted on September 28, 2011 and an IRB closure letter was sent on the same date. WIRB acknowledged receipt of study closure notification and closed the study effective 9/30/11.
	A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multinational Trial, to Assess the Prevention of Thrombotic Events with Ticagrelor Compared to Placebo on a Background of Acetyl Salicylic Acid

COMPLETED CARDIOLOGY STUDIES

	(ASA) Therapy in Patients with History of Myocardial Infarction (Pegasus-TIMI 54) Protocol: D5132C00001 IRB of Record: Hopkins (NA_00044147) The primary objective of the study is to compare the effect of long-term treatment with ticagrelor vs. placebo on a background of acetyl salicylic acid (ASA) on the event rate of the composite of cardiovascular death, non-fatal myocardial infarction (MI), or non-fatal stroke in patients with history of MI and high risk of developing atherothrombotic events. The primary efficacy variable is time to first occurrence of any event after randomization from the composite of cardiovascular death, non-fatal MI, or non-fatal stroke. The protocol was submitted to and approved by the Suburban Hospital Research Review Committee (SHRRC) and JHM eIRB. Prior to contract execution, Suburban Hospital was notified by the CRO, TIMI Group, that the site would not have sufficient time to make significant enrollment contribution and it was decided that it was in Suburban's best interest to comply with the sponsor recommendation. The JHM eIRB was notified 11/23/11.
	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of SCH 530348 in Addition to Standard of Care in Subjects with a History of Atherosclerotic Disease: Thrombin Receptor Antagonist in Secondary Prevention of Atherothrombotic Ischemic Events (TRA 2°P – TIMI 50) Protocol: P04737 IRB of Record: WIRB The principal goal of the study is to evaluate the hypothesis that SCH 530348 when administered orally and added to standard of care will reduce the incidence of atherothrombotic ischemic events relative to standard of care alone, as measured by the composite of

COMPLETED CARDIOLOGY STUDIES

	cardiovascular death, myocardial infarction (MI), stroke, and urgent coronary revascularization. The benefit of antiplatelet agents in secondary prevention of atherothrombotic events is well established. The present trial is designed to determine whether inhibition of platelet PAR-1 receptor to stimulation by thrombin in addition to standard-of-care antiplatelet therapy (eg aspirin, thienopyridines) can result in further incremental benefit, as determined by reduction in the incidence of atherothrombotic events relative to standard of care alone, in subjects with established CAD, CVD or PAD. Screening started in March 2009 and 9 subjects were enrolled. Enrollment ended in November 2009 and follow-up was completed through December 2011. The close out visit was conducted in March 2012 at this site and WIRB, the IRB of record was notified. Results presented at ACC 2012 found inhibition of PAR-1 with vorapaxar reduced the risk of cardiovascular death or ischemic events in patients with stable atherosclerosis who were receiving standard therapy. However, it increased the risk of moderate or severe bleeding, including intracranial hemorrhage.
	Can HDL Infusions Significantly QUicken Atherosclerosis REgression? (CHI SQUARE): A Phase II Multi-Center, Double-Blind, Ascending Dose, Placebo-Controlled, Dose-Finding Trial of CER 001 or Placebo in Subjects with Acute Coronary Syndrome (Protocol CER 001 CLIN 002) <u>IRB of Record: Hopkins (NA_00046966)</u> To assess the impact of six intravenous infusions of 3, 6, or 12 mg/kg CER-001 or placebo, given at weekly intervals, on atherosclerotic plaque volume, as measured by coronary IVUS, when administered to subjects presenting with an Acute Coronary

COMPLETED CARDIOLOGY STUDIES

	Syndrome (ACS) (STEMI, non-STEMI or unstable angina). The protocol has been approved by the Suburban Hospital Research Review Committee (SHRRC) and the JHM eIRB. Screening began in September 2011. Four subjects have enrolled and seven subjects have screened failed at Suburban Hospital. Enrollment was completed in August 2012. Suburban's last follow up was conducted in December 2012. Close out visit for this study was conducted on June 12, 2013. JHM eIRB was notified of the close of the study and it was acknowledged by the IRB on June 18, 2013.

SUBURBAN HOSPITAL

JOHNS HOPKINS MEDICINE

Appendix B: NIH Heart Center Research Screenings and Enrollment

NIH Heart Center at Suburban Research
Screening and Enrollment
(NIH and Industry)

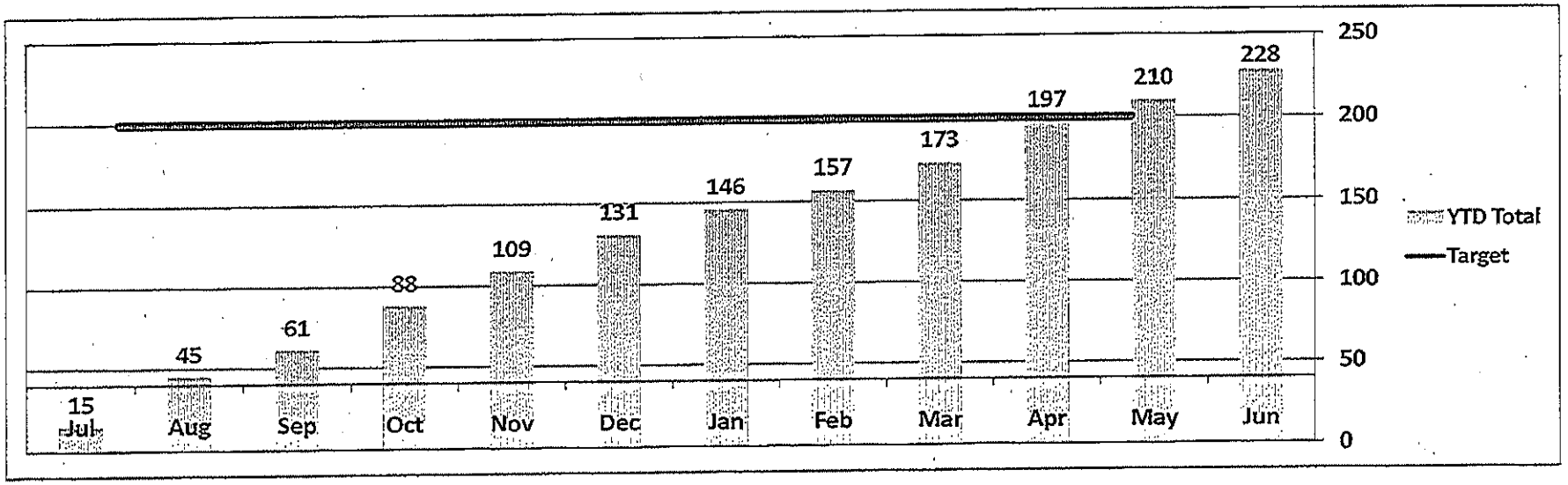
Month	Cardiology Screened Inpatient	Cardiology Screened Outpatient	Cardiology Total Screened	Cardiology Enrolled	Cardiology Screen Failed	Cardiology Refused	OHS Screened	OHS Enrolled	OHS Screened Failed	OHS Refused
Jan-12	157	4	161	2	0	5	24	2	4	0
Feb-12	179	1	180	11	0	2	26	3	0	2
Mar-12	153	1	154	4	2	5	25	7	3	2
Apr-12	142	5	147	4	0	2	26	0	5	1
May-12	158	1	159	5	2	5	29	0	3	1
Jun-12	169	2	171	1	1	0	29	2	1	2
Jul-12	165	3	168	1	1	0	23	2	3	0
Aug-12	141	5	146	3	0	0	20	3	1	1
Sep-12	123	2	125	3	0	0	15	1	2	1
Oct-12	131	1	132	1	0	1	20	2	2	2
Nov-12	138	2	140	1	0	1	19	1	3	2
Dec-12	108	2	110	1	0	3	24	3	1	1
TOTALS	1764	29	1793	37	6	24	280	26	28	15
Jan-13	126	1	127	4	0	3	16	2	3	3
Feb-13	104	2	106	2	0	0	18	1	2	1
Mar-13	118	2	120	0	0	2	25	2	0	1
Apr-13	134	2	136	3	0	2	29	1	1	3
May-13	138	2	140	3	1	1	17	2	0	1
Jun-13	97	1	98	0	0	0	31	5	3	0
Jul-13	123	3	126	2	0	0	43	5	2	6
Aug-13	121	1	122	1	0	4	38	0	0	8
Sep-13	128	55	183	0	0	2	20	2	1	0
Oct-13	142	178	320	4	2	14	37	2	0	3
Nov-12										
Dec-12										
TOTALS	1231	247	1478	19	3	28	274	22	12	26

October 31, 2013

SUBURBAN HOSPITAL
JOHNS HOPKINS MEDICINE

Appendix C: Volume

CARDIAC SURGERY CON VOLUME TRACKING	SUBURBAN HOSPITAL FISCAL YEAR 2013													
	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Needed to reach 200:
Total CON Cases	15	30	16	27	21	22	15	11	16	24	13	18	228	TARGET MET



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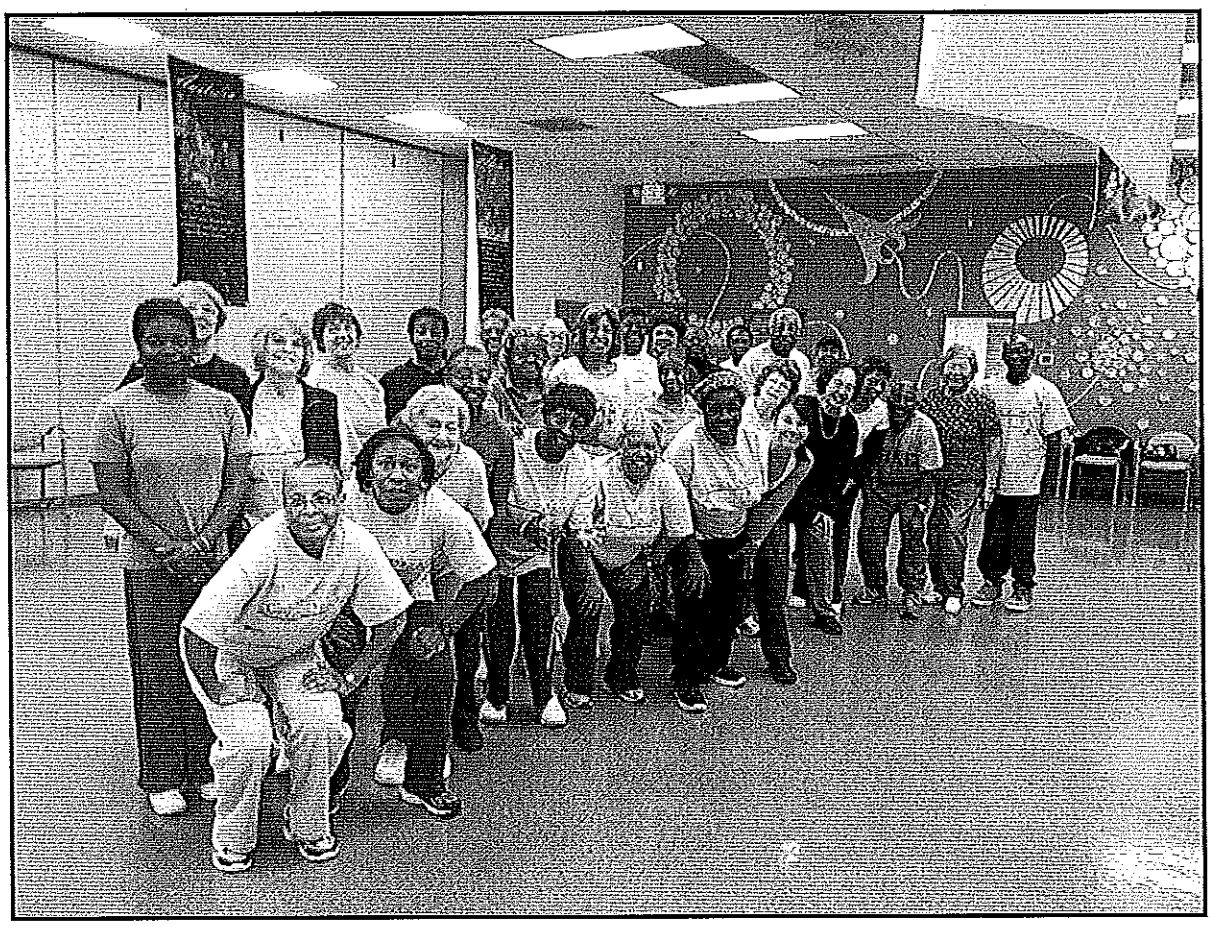
Appendix D:

Fiscal Year 2013 Suburban Hospital Report – Cardiovascular Outreach in Southern Maryland



Fiscal Year 2013 Suburban Hospital Report
Cardiovascular Outreach in Southern Maryland

Submitted on behalf of the
Community Health & Wellness Department
Suburban Hospital, a Member of Johns Hopkins Medicine

SUBURBAN HOSPITAL
JOHNS HOPKINS MEDICINE

Introduction

Celebrating its seventh year, the NIH Heart Center at Suburban Hospital continues to be a national leader in cardiac care and surgery. The NIH Heart Center at Suburban Hospital is also dedicated to serving and addressing the cardiovascular health needs and disparities among the nearby Southern Maryland counties of Prince George's, Calvert and St. Mary's. In FY 2013, Suburban Hospital successfully served more than 12,300 Southern Maryland residents who participated in 618 cardiovascular prevention and management activities/events such as health education initiatives, exercise and wellness programs, health seminars and screenings. Suburban partnered with nearly sixty hospitals, faith-based organizations, senior and recreation centers, non-profit organizations, academic institutions and government agencies to make high level impact on the health outcomes of Southern Maryland community members.

In FY 2012, Suburban Hospital dedicated $20.4 million in community benefit contributions including, community health improvement programs, screenings, classes and charity care services to support the needs of Montgomery County residents. Additionally, more than 2,700 health improvement events occurred reaching a total of 86,606 community members. During FY 2013, the NIH Heart Center at Suburban Hospital continues to make a financial commitment to the community members living in Southern Maryland by providing $70,000 towards in-kind and financial support of cardiac outreach programs and services. This support has funded senior exercise and fitness programs, worksite wellness, cardiac programming and initiatives, heart healthy cooking demonstrations, cardiovascular health education presentations and various health screenings throughout Southern Maryland.

The following report will serve to highlight some of the key programs and initiatives that have been success models of delivering quality cardiovascular-focused community outreach. The highlighted programs show evidence of improving or helping to maintain a high standard of quality of life, aging well in place, improving physical, psychological and sociocultural status and preventing cardiac and other related chronic conditions and complications.

Community Program Highlights in Prince George's County

Senior Shape Exercise Program at the Gwendolyn Britt Senior Activity Center

Health Priorities Addressed: Cardiovascular Disease and High Blood Pressure, Obesity, Diabetes, Behavioral/Mental Health, Cancer

Suburban Hospital's Senior Shape Exercise Program continues to be one of the most popular and well-attended classes offered at the Gwendolyn Britt Senior Activity Center located in North Brentwood, MD. First introduced in Prince George's County in 2005, Senior Shape is offered free to residents 50 years and older. Senior Shape provides participants with a safe, low-impact aerobic, exercise regimen that focuses on strength and weight training, balance,

Seniors exercise their way to good health in the Senior Shape Exercise Program at the Gwendolyn Britt Senior Activity Center, Prince George's County

flexibility and stretching, and aerobic activity for optimal cardiovascular benefits. The exercise program is led by a certified exercise instructor and meets twice a week for 45 minutes. During FY 2013, each class averaged between 25-30 participants, amounting to approximately 3,120 seniors throughout the year.

In addition to improving cardiovascular health, the aerobic exercise class also addresses other major health priorities such as, reducing overweight and obesity, preventing and/or managing diabetes, reducing risk for cancer and improving mental health status by providing a social support and networking outlet.

Every week, regular blood pressure screenings are conducted at the Gwendolyn Britt Senior Activity Center by the Cardiovascular Health Promotions Coordinator from Suburban Hospital. The blood pressure screening is free and offered to the Senior Shape participants, Nutrition Program participants and anyone else who may be interested. The blood pressure screening allows Senior Shape participants to track and monitor their pressure from week to week and see the positive impact regular exercise can have on their blood pressure.

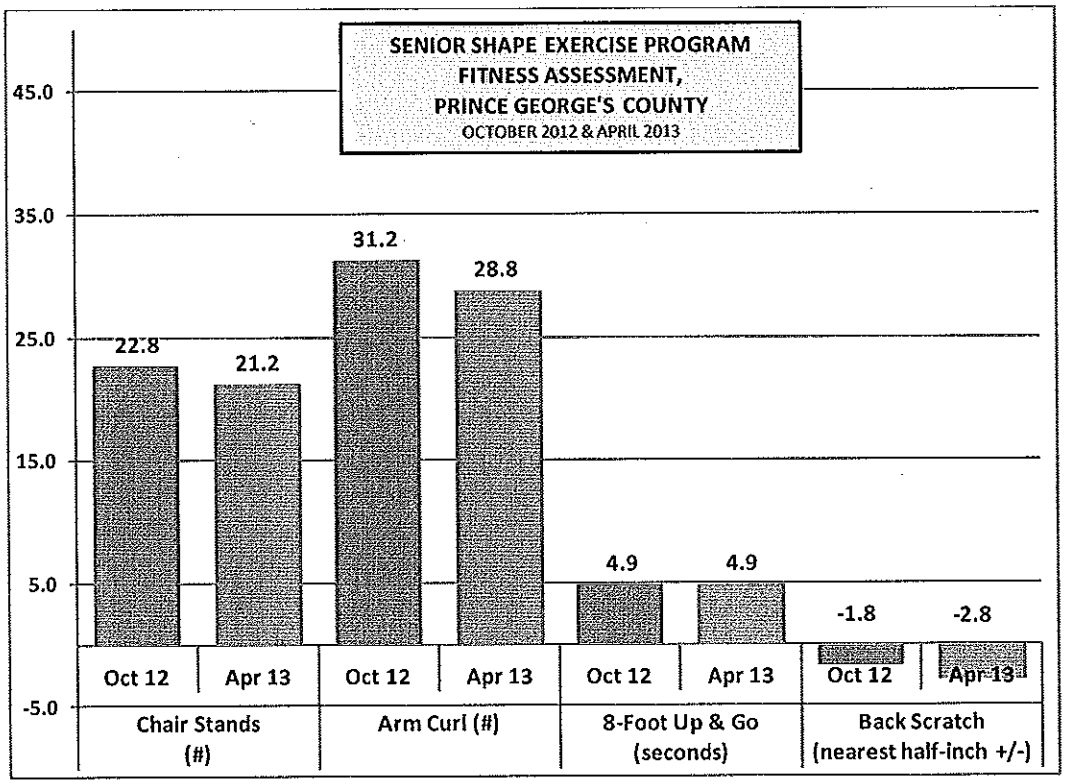
Senior Shape Exercise Program Fitness Assessment

Beginning in March 2010, every six months the seniors participate in a fitness assessment that tests their physical ability in four areas of fitness: chair stand, arm curl, 8-foot up-and-go, and back scratch test. Most recently, data from October 2012 and April 2013 was assessed to exhibit the impact of the exercise program. The results below (**Graph A.**) reflect the average score from a sample of 17 participants who completed the assessment in both October and April. Over the six month period, results show that the seniors were able to maintain a consistent level of strength and endurance, only fluctuating in the averages slightly.

For example, the 8-foot up-and-go test reflects the average amount of time (in seconds) it takes for the individual to stand up from a seated position and walk or run around a place marker 8-feet away and return to the chair. The results demonstrate that from October to April the seniors were able to maintain a steady level of fitness in their agility and response time.

In conclusion, these results are encouraging and could indicate that the seniors are living a better, more active lifestyle and potentially reducing the incidence and risk of cardiovascular disease and other related chronic conditions along with preventable falls and/or injuries due to improved balance, strength and agility. The Senior Shape Exercise Program will continue to include the health assessment to monitor the fitness levels of the participants and to encourage more seniors to reach their optimal active lifestyle goals.

Graph A.



Suitland Dine & Learn Program

Health Priorities Addressed: Cardiovascular Disease and High Blood Pressure, Obesity, Diabetes, Cancer

Since its inception in January 2008, the Suitland Dine & Learn Program has become one of the most successful health improvement initiatives in Prince George's County. The NIH Heart Center at Suburban Hospital has supported the program, now in its sixth year, and collaborates with the Maryland-National Capital Park and Planning Commission's Department of Parks and Recreation (M-NCPPC) and Prince George's County Health Department to bring the county residents a comprehensive and credible health education program.

The Suitland Dine & Learn Program is a free monthly health education program available to under- and/or uninsured residents of Suitland and surrounding communities in Prince George's County. The program's goal is to reduce cardiovascular health disparities and related co-morbidities among Prince George's County residents. Each monthly Dine & Learn session provides attendees with a blood pressure screening, an exercise demonstration led by a

certified instructor, a nutrition education lecture by a registered dietician, and a heart healthy cooking demonstration led by a personal chef who is also a registered dietician.

The Suitland Dine & Learn team preps a seasonal salad for participants to enjoy at the Suitland Community Center, Prince George's County

In addition to addressing heart health and high blood pressure, the program also aims to reduce the prevalence and incidence of obesity and diabetes by providing low-calorie, low-fat heart and diabetes-friendly recipes and by engaging in various exercises that appeal to everyone and do not require a gym. The Suitland Dine & Learn Program also works to lower the incidence of cancer risk by encouraging a diet rich in leafy greens and antioxidants.

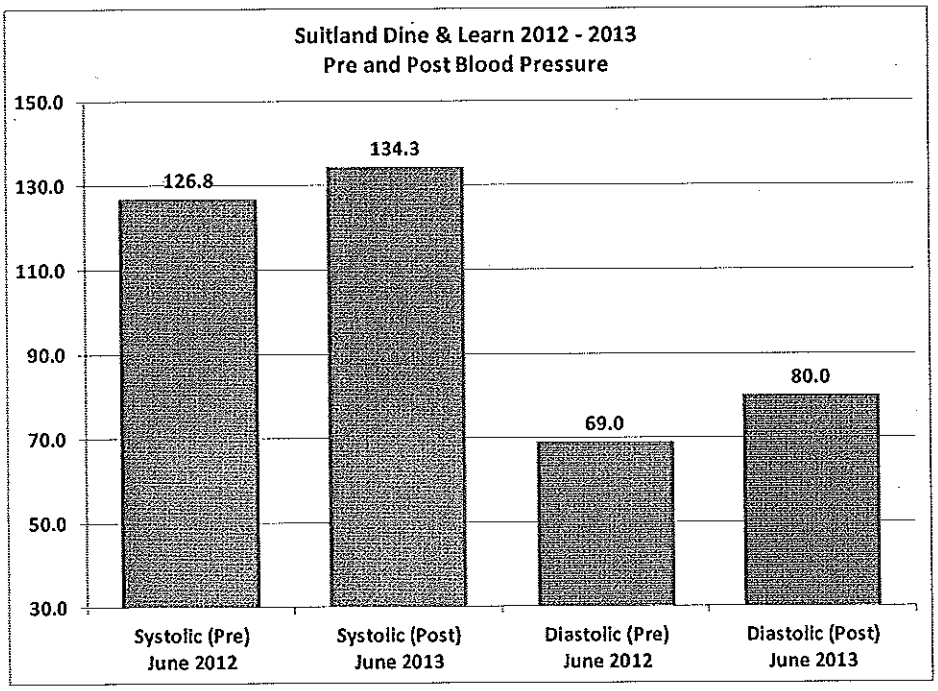
As the program becomes more established in the community, so does the participation and popularity. The average number of attendees per session was 24 individuals, resulting in more than 235 participants throughout the year.

Suitland Dine & Learn Program Health Assessment

To evaluate the program and its effectiveness, the NIH Heart Center at Suburban Hospital takes the lead in conducting a free health assessment twice a year; once at the beginning of the program (January) and six months later (June). The pre- and post-health assessment includes a total cholesterol screening, blood pressure, weight and waist circumference. This year, the health assessment analyzed data results from June 2012 to June 2013. Of the 23 participants measured in June 2012 and the 22 measured in June 2013, only 8 individuals completed both assessments to evaluate pre- and post-test (n = 8), of which seven were female and one was a male. The results from the health assessment are shown below.

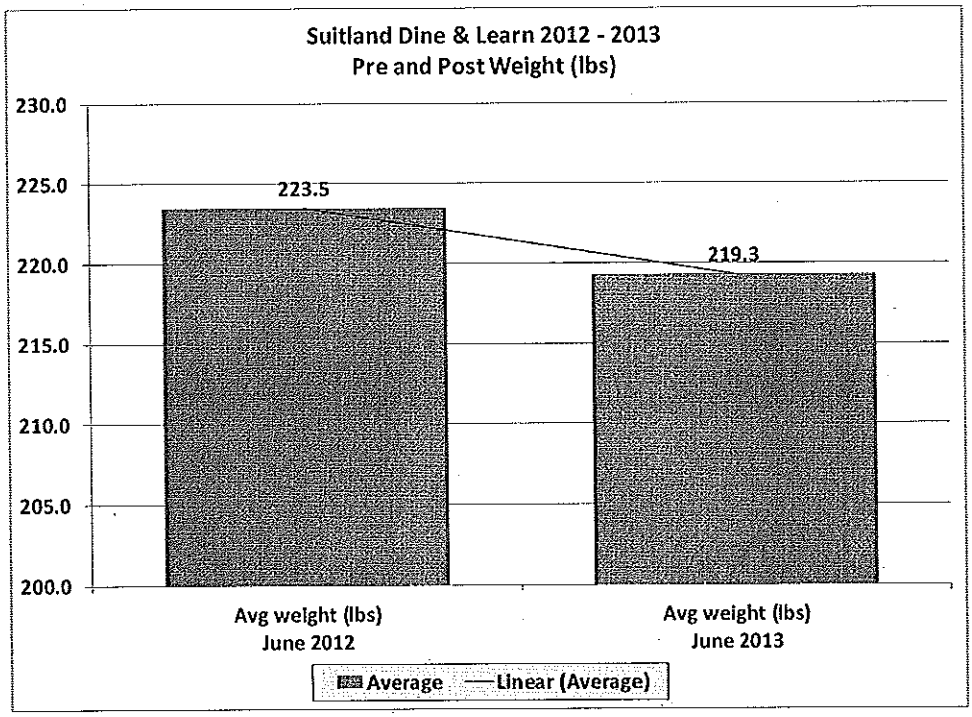
The first graph below (**Graph 1.**) displays the blood pressure over the course of one year. While the results show an increase in the systolic (from 127 to 134) and the diastolic (69 to 80) from June 2012 to 2013, the diastolic remains in the normal range and the systolic is in the 'pre-hypertensive' range. Nonetheless, this is an area to continue improving to less than 120/80.

Graph 1.



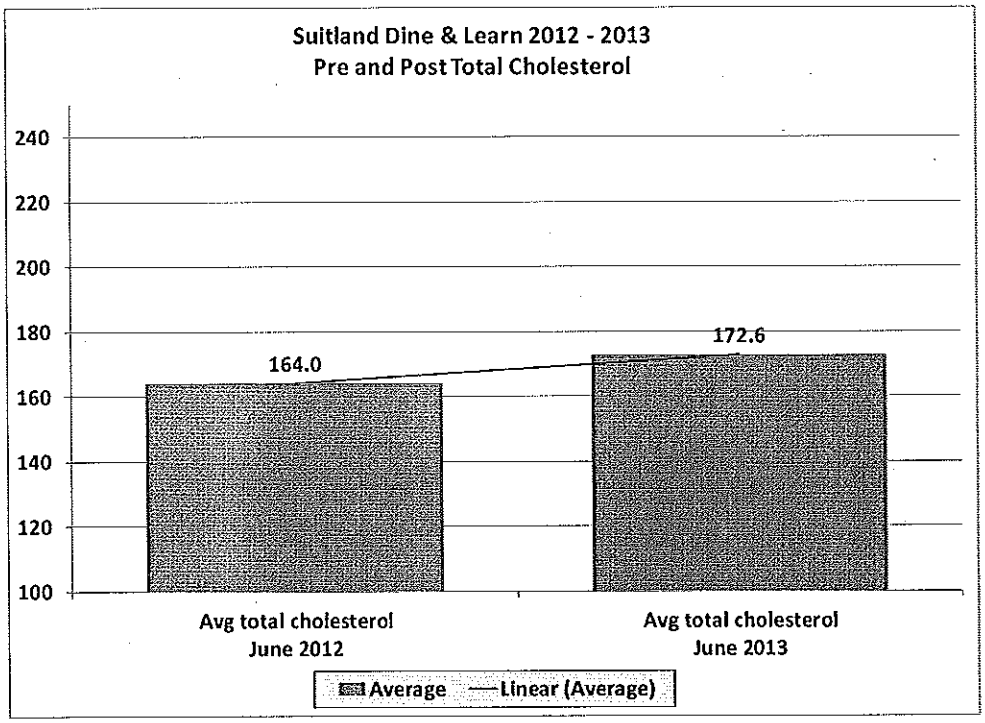
Graph 2 displays the overall weight loss (lbs.) of the sample group. The Suitland Dine & Learn participants lost an average of four (4) lbs. between June 2012 and 2013, which reflects an improvement from last year's average weight loss of two (2) lbs.

Graph 2.



Graph 3 presents the results from the total cholesterol screening. Normal total cholesterol is less than 200. While the average total cholesterol results did not decrease from 2012 to 2013, the overall score is less than 200 and exhibits a normal level (172.6 in June 2013). This indicates that the participants are engaging in healthier lifestyle behaviors and lowering their risk factors for cardiovascular disease and other chronic conditions.

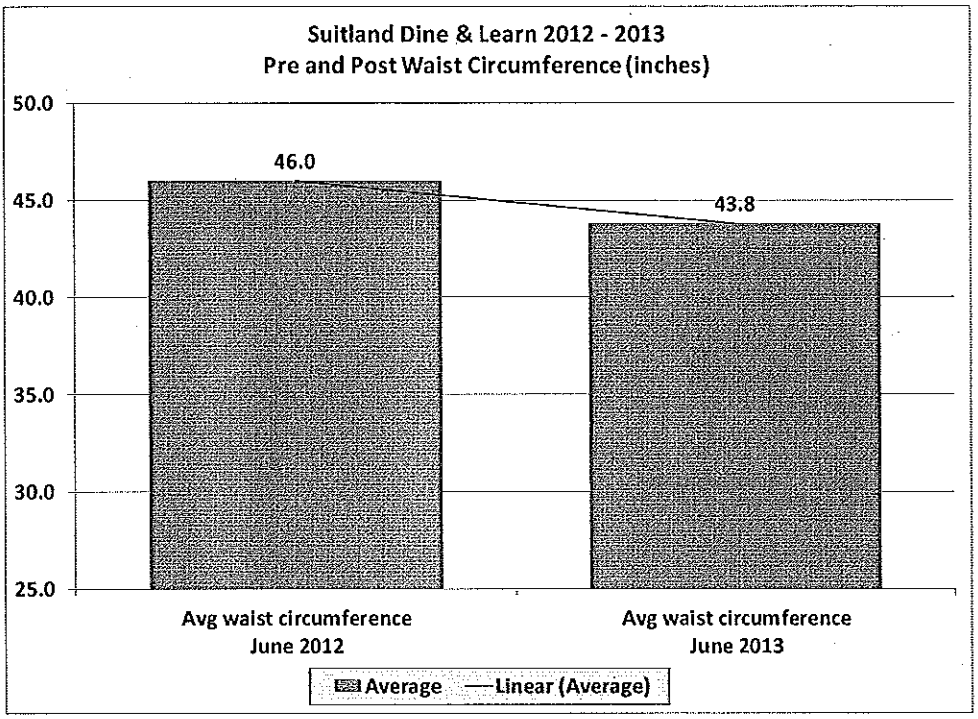
Graph 3.



Graph 4 exhibits the sample group's average waist circumference in inches. According to the U.S. Department of Health and Human Services (DHHS), a woman's waist circumference should be 35 inches or less (men should be 40 inches or less). Waist circumference is a practical and effective tool to assess abdominal fat for chronic disease risk. A higher waist circumference (or a greater level of abdominal fat) is associated with an increased risk for type 2 diabetes, high cholesterol, high blood pressure and heart disease.

The analysis reveals a reduction in the average waist circumference from 46 inches in June 2012 to 43.8 inches in June 2013, a difference of 2.2 inches. Taking the weight loss data in conjunction with the waist circumference decrease, the analysis shows that while there is still room for improvement to reach the recommended circumference, participants are taking positive steps towards living a healthier lifestyle.

Graph 4.



Community Program Highlights in Calvert County

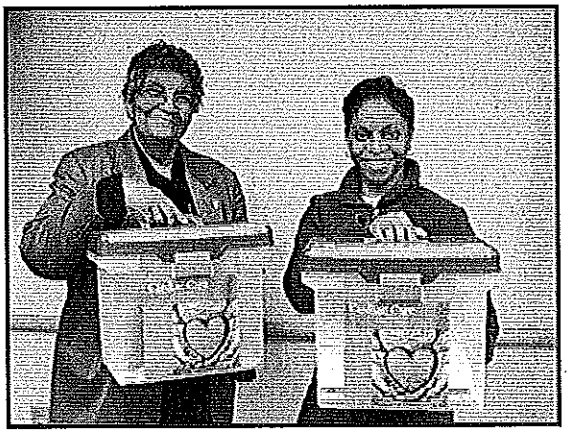
Calvert Memorial Hospital Health Ministry Team Network: Blood Pressure Kit Initiative

Health Priorities Addressed: Cardiovascular Disease and High Blood Pressure, Obesity, Diabetes

The NIH Heart Center at Suburban Hospital continues to enrich and strengthen its partnership with Calvert Memorial Hospital (CMH) Health Ministry Team Network. The Health Ministry Team Network partners with area ministries to build a healthier community and promotes healthy lifestyles within the church community. Currently, the Network has 22 active member churches that meet monthly to address a wide range of health topics. Suburban Hospital participates in these monthly meetings to serve as a resource and support for the Health Ministry Team Network members.

Since 2008 Suburban Hospital and the Health Ministry Team Network have partnered to deliver the Blood Pressure Kit Initiative, which allows for free monthly blood pressure screenings of community members before or after church service. Suburban Hospital provides each church with a "kit" including, a stethoscope, cuff, tracking cards, medical health record cards, health education information, and alcohol pads. A Health Ministry Team leader who is typically a nurse or other medical professional volunteers each month to take routine blood pressure screenings at their respective congregation. Each month, the readings are recorded so the

nurse and individual can monitor any changes. This interaction between the community member and a Health Ministry leader establishes trust, credibility and openness for discussing other health concerns the individual may have. Often times, the volunteer nurse is counseling on matters of diabetes, proper nutrition, incorporating a more active lifestyle and how to manage a healthy weight.



Patuxent United Methodist Church and St. Mary of the Assumption Catholic Church each display their new blood pressure kit, Calvert County

Five (5) churches have been a part of the Blood Pressure Kit Initiative since 2008:

- Crossroad Christian Church (St. Leonard)
- Huntingtown United Methodist Church (Huntingtown)
- Middleham/St. Peter's Parish (Lusby)
- Our Lady Star of the Sea Catholic Church (Solomons)
- Waters Memorial United Methodist Church (St. Leonard)

During FY 2013, 925 blood pressure screenings were completed among the five churches.

In March 2013, two new churches joined the Blood Pressure Kit Initiative – 1) Patuxent United Methodist Church in Huntingtown and 2) St. Mary of the Assumption Catholic Church in Upper Marlboro, Maryland. Additionally, four more parishes, of which all are predominantly African American, will begin conducting routine blood pressure screenings in early 2014.

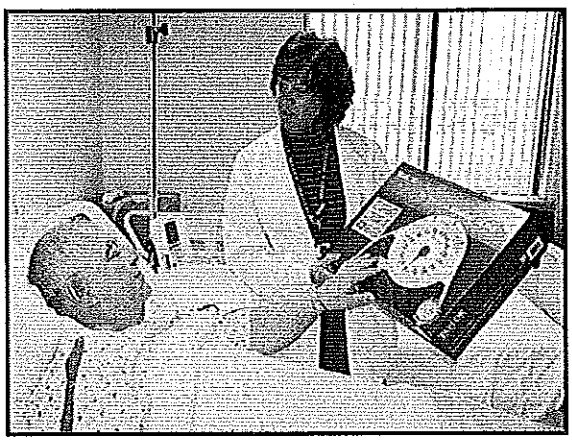
Community Program Highlights in St. Mary's County

Congestive Heart Failure Program at MedStar St. Mary's Hospital

Health Priorities Addressed: Cardiovascular Disease and High Blood Pressure, Obesity, Diabetes

Since 2007, MedStar St. Mary's Hospital (SMH) of Leonardtown, Maryland and Suburban Hospital have partnered on the Congestive Heart Failure (CHF) program at MedStar St. Mary's Hospital. The CHF program provides patients with inpatient and outpatient care, education and tools to reduce their readmission rate and further complications. Like many hospitals across the United States, St. Mary's Hospital faces the challenge of congestive heart failure being the number one cause of readmission. St. Mary's Hospital has worked diligently to reduce the readmission rate by leading a comprehensive program that incorporates inpatient rounds to heart failure patients. SMH provides in-depth patient education and the necessary tools, such as, pillboxes, written take-home materials and educational DVD's, to help patients become successful at self-management. With the support of the NIH Heart Center at Suburban

Hospital, patients who cannot afford to purchase their own scale are provided with one at no cost to them for weight management at home.



MedStar St. Mary's Hospital nurse discusses with congestive heart failure patient how to properly use his new scale, St. Mary's County

In FY 2013, 70 scales were provided to heart failure patients in financial need who could not pay for this beneficial tool on their own. The value of this contribution totaled to $1,881.50. Daily weights have allowed patients to identify fluid collection early and report it to their physician, thereby decreasing readmissions. It also helps the patients to practice their self-management skills at home and become more self-reliant. The Congestive Heart Failure program has been incorporated into the Readmission Reduction Initiative at MedStar St. Mary's Hospital and they report that their heart failure patient readmission rate has consistently been lower than 25 percent. Suburban Hospital plans to continue this collaboration and will track and monitor the CHF program with annual progress updates by MedStar St. Mary's Hospital.

Challenges

As with any health program, obstacles are faced in the process of delivering quality, community-based health education programming and initiatives. While the cardiovascular outreach efforts have been successful in reaching and improving lives, they have also been met with some challenges. One of those challenges is encouraging the same Suitland Dine & Learn participants to participate in both the pre- and post-health assessment so there is a more representative sample size when analyzing the data. This will yield to more accurate data results and conclusions. Other ongoing challenges are conducting sufficient promotion and social marketing of free health events and screenings, encouraging community members to attend the various classes and programs so Suburban Hospital can continue to offer them, and balancing where and what events the NIH Heart Center at Suburban Hospital supports so the individuals who need the services the most, are reached.

Program Goals and Improvement Targets

The following outlines a few key program goals and projected improvement targets for FY 2014.

- Increase recognition of the NIH Heart Center at Suburban Hospital in Southern Maryland through promotion, publications and education.

- Provide financial support in FY 2014 for home scales to MedStar St. Mary's Hospital's Congestive Heart Failure program.
- Create a competitive scholarship fund initiative to support a cardiovascular or cardiac-related program for the Calvert Memorial Hospital Health Ministry Team Network.
- Enhance collaboration and education with the Prince George's County youth via the Youth Garden program and/or Safe Nights at the Suitland Community Center.
- Identify a second site for expanding the Suitland Dine & Learn program by July 2014.
- 50 percent of Senior Shape Exercise Program participants will improve on at least two (2) of the four (4) fitness assessment areas during FY 2014.
- Conduct at least one (1) Freedom From Smoking Cessation Program in Prince George's County.
- Explore opportunities for partnering with at least one (1) Prince George's County hospital and identify areas where the NIH Heart Center at Suburban Hospital can support their cardiovascular health improvement initiatives.

Supplemental Documents

For a more specific outline of the total number and types of events and total interactions with the communities served, please refer to the supplemental document entitled "CON Report Volume FY 2013."

The attached spreadsheet demonstrates the total number of events, total interactions, and racially/ethnically diverse interactions in Southern Maryland from October 1, 2012 to September 30, 2013. The data reflects the NIH Heart Center at Suburban Hospital's strategic approach to direct its program implementation in communities that suffer higher rates of health risk factors and health disparities and therefore, could potentially benefit more from culturally and linguistically appropriate health education and improvement initiatives. The NIH Heart Center at Suburban Hospital is committed to improving the cardiovascular health and wellness of its neighboring counties by working with partners in the community to deliver comprehensive, preventive and sustainable health improvement initiatives.